

EXAKT-PAK[®]

ASSEMBLY INSTRUCTIONS

This package is specifically designed to transport vials not to exceed 16mm in diameter and 125mm in length. It MAY NOT transport a liquid amount in excess of 15 mL in any one secondary container NOR may it transport any additional containers except those that fit in the cavities in the package.-

IMPORTANT - READ OTHER SIDE FIRST

1



Remove the caps and the clear plastic containers from the box.

2



Pull up on and separate the two ends of the absorbent material in the plastic container.

3



Place your specimen vial UPRIGHT in the plastic container.

4



Using your finger, gently push the vial and the absorbent sheath to the bottom of the plastic container.

5



After pushing any excess absorbent material into the top of the container, screw the cap on tightly.

6



Place the sealed plastic container in the box making sure that the bottom of the container reaches the bottom of the box.

7



Fill the cavity with dry ice. If the dry ice is pelletized, shake the box so that the pellets fill underneath the tray holding the containers.

8



Place the top piece of white EPS foam on top of EPS sides.

9



Regulations require an itemized list of contents. Place this list and any other documentation on top of the white EPS foam lid.

10



Loosely fold the plastic liner bag on top of the EPS foam. Do not seal it. Gas from the dry ice must be able to escape.

11



Close the inner and outer box flaps. Use the 2" x 10" strip of tape and seal the top seam of the box. Make sure that the seam is fully sealed across the top with the excess tape running down the sides.

12



Using the 2" x 10" strips of tape, seal both side seams making sure that half the tape is on the top of the box and the other half is on the side of the box.

13



Placement of hazard labels for dry ice and infectious substances. Do not put address labels on this panel.

ATTENTION:

READ ALL OF THE INTRODUCTION AND THE PACKAGING INSTRUCTIONS BEFORE USE. IT IS RECOMMENDED THAT YOU REVIEW ALL OF THE INFORMATION PRIOR TO COLLECTING THE SPECIMEN.

TO INSURE THE SAFETY OF ALL PERSONNEL WHO COME IN CONTACT WITH A MEDICAL SPECIMEN, VARIOUS REGULATORY AGENCIES CALL FOR "UNIVERSAL PRECAUTIONS" AS AN APPROACH TO INFECTION CONTROL. THESE "UNIVERSAL PRECAUTIONS" INSTRUCT THAT ALL POTENTIALLY INFECTIOUS MATERIALS (NON-STERILIZED) BE HANDLED AS IF THEY WERE INFECTIOUS. TO THAT END, WHEN PROPERLY ASSEMBLED, THIS PACKAGING SYSTEM HAS BEEN DESIGNED TO COMPLY WITH ALL KNOWN REGULATORY AGENCIES' REQUIREMENTS FOR THE SAFE TRANSPORT OF INFECTIOUS SUBSTANCES. THIS PACKAGING SYSTEM HAS BEEN CERTIFIED BY AN ACCREDITED, INDEPENDENT TESTING FACILITY THAT IT COMPLIES WITH THE U.S. DEPARTMENT OF TRANSPORTATION PACKAGING REQUIREMENTS FOR SHIPPING INFECTIOUS SUBSTANCES. IF PROPERLY ASSEMBLED THIS PACKAGING SYSTEM IS ALSO IN COMPLIANCE WITH THE INTERNATIONAL CIVIL AVIATION ORGANIZATION (ICAO [IATA]) REQUIREMENTS AS WELL.

PRIOR TO ASSEMBLY:

1. Contact the receiving lab, the device manufacturer or the person responsible for performing the analysis on the specimen(s) to obtain any specific instructions pertinent to shipping the specimen(s).
2. Follow any applicable regulatory agency guidelines for maintaining chain of custody.
3. This specially designed packaging system has been certified to comply with U.S. Department of Transportation (DOT) packaging requirements governing the transport of an infectious substance. All packages are supplied complete and the shipper must not make substitutions or modifications. Check with your shipping department, risk management official, regulatory affairs department, the U.S. Department of Transportation or other regulatory agencies for compliance with other regulations governing the shipping of your specific material or specimen.

LABELING & DOCUMENTATION

A variety of internal and external labels are included in this package. It is, however, the responsibility of the shipper to choose the appropriate labels regardless of whether they are included in this package or not, and to comply with DOT, ICAO (IATA) or individual shipper regulations regarding labeling. The inclusion of labels in this package is a matter of

convenience and is not meant to instruct the shipper in the labeling requirements that need to be met. NOTE: This packaging system does not include the appropriate shipping documents that must accompany this package. It is the responsibility of the shipper to insure that the appropriate documentation is presented to the common carrier.

WARNING: ALL PACKAGES ARE SUPPLIED COMPLETE AND THE SHIPPER MUST NOT MAKE SUBSTITUTIONS OR MODIFICATIONS. FAILURE TO HEED THIS WARNING WILL INVALIDATE PACKAGE COMPLIANCE. THE SELLER MAKES NO CLAIM AS TO THE SUITABILITY OF THESE PACKAGES FOR THE CUSTOMER'S PRODUCT. DETERMINATION OF THE SUITABILITY IS THE RESPONSIBILITY OF THE CUSTOMER.

IN ADDITION, THESE ASSEMBLY INSTRUCTIONS ARE SOLELY FOR THE PURPOSE OF INSTRUCTING A SHIPPER IN THE PROPER ASSEMBLY OF THIS PACKAGING SYSTEM. THE SELLER IS NOT PROVIDING ANY TRAINING IN OR INSTRUCTIONS ON THE TRANSPORT OF HAZARDOUS MATERIALS. IN NO WAY SHOULD THE SHIPPER CONSIDER THAT, BY FOLLOWING THESE INSTRUCTIONS, HE/SHE IS RELEASED FROM ANY OR ALL OF HIS/HER LEGAL RESPONSIBILITIES IN SHIPPING HAZARDOUS MATERIAL. THE LIABILITY FOR SHIPPING HAZARDOUS MATERIALS IS

SOLELY THE SHIPPER'S RESPONSIBILITY AS OUTLINED IN THE CODE OF FEDERAL REGULATIONS (CFR) TITLE 49 AND THE INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) DANGEROUS GOODS REGULATIONS. THE USE OF THIS PACKAGING SYSTEM DOES NOT RELEASE THE SHIPPER FROM ANY OF THE SHIPPER'S RESPONSIBILITIES SET FORTH IN ANY LOCAL, STATE, FEDERAL OR INTERNATIONAL REGULATIONS. IMPROPER ASSEMBLY OF THIS SYSTEM OR USE OF THE SYSTEM FOR OTHER THAN ITS INTENDED PURPOSE WILL ALSO INVALIDATE PACKAGE COMPLIANCE.

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED HEREIN, EXAKT TECHNOLOGIES, INC. MAKES NO WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO THIS PACKAGING SYSTEM, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY THAT THE PACKAGING SYSTEM IS FIT FOR ITS INTENDED PURPOSE.

In case of any material defect in the packaging system, EXAKT Technologies, Inc. shall be liable only for the unit price of the packaging system, and shipping costs, and in no event shall EXAKT Technologies, Inc., its shareholders, officers directors, agents, employees, successors or assigns be liable for incidental or consequential damages.

Any issues concerning the construction, manufacture or use of the packaging system not governed by federal law or regulation shall be governed by the laws of the State of Oklahoma.

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